JUN 10 2010

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the SIDEKICK® Circular Fixator System: Struts and Hinges.

A.1. Submitted By:

Wright Medical Technology, Inc.
5677 Airline Rd
Arlington, TN 38002

Date: April 23, 2010

Contact Person:

Megan McCagh
Regulatory Affairs Specialist
(901) 867-4120

A.2. Proprietary Name: **SIDEKICK® Circular Fixator System: Struts and Hinges**

Common Name: External Fixation System

Device Classification Regulation: Single/multiple component metallic bone fixation appliances and accessories -Class II per 21 CFR section 888.3030

Device Product Code & Panel: Orthopedics/87/KTT

A.3. Predicate Device: R & R External Fixation (Ring Fixator) (K052005)

A.4. Device Description

The SIDEKICK® Circular Fixator System: Struts and Hinges is a dynamic frame that can change position or orientation from the beginning of treatment to the end of treatment for correcting deformities in soft tissue or bone. The system allows precise, controlled compression/distraction. The hinges are used to create a point of rotation and/or angulation between levels of ring fixation on the frame. The rotation/angulation of the struts is used as compressors/distractors and which provide gradual or acute movement.

A.5. Intended Use

The SIDEKICK® Circular Fixator System: Struts and Hinges and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects. The SIDEKICK® Circular Fixator System: Struts and Hinges is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

A.6. Technological Characteristics Comparison

The subject SIDEKICK® Circular Fixator System: Struts and Hinges and the legally marketed predicate R & R External Fixation (Ring Fixator) have the same indications, are used at the same anatomical sites, and are both multi-piece designs.

The subject SIDEKICK® Circular Fixator System: Struts and Hinges differs from the legally marketed predicate R & R External Fixation (Ring Fixator) in the number of axes of rotation, material and type of bridge element.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence was shown through static compressive stress testing. The results of the test show that the subject SIDEKICK® Circular Fixator System: Struts and Hinges can be expected to perform at least as well as the legally marketed predicate R & R External Fixation (Ring Fixator).

The safety and effectiveness of the SIDEKICK® Circular Fixator System: Struts and Hinges is adequately supported by the substantial equivalence information, materials information, and comparison of design characteristics provided within the Premarket Notification.

B.2. Substantial Equivalence – Clinical Evidence

N/A

B.3. Substantial Equivalence - Conclusions

The indications for use of the SIDEKICK® Circular Fixator System: Struts and Hinges are identical to the predicate device. The design features and materials of the subject device are substantially equivalent to those of the predicate device. The substantial equivalence information, materials information, and analysis data provided within this Premarket Notification adequately supports the safety and effectiveness of the SIDEKICK® Circular Fixator System: Struts and Hinges.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
c/o Ms. Megan McCagh
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

JUN 10 2010

Re: K100137
Trade/Device Name: SIDEKICK® Circular Fixator System: Struts and Hinges
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: May 10, 2010
Received: May 13, 2010

Dear Ms. McCagh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100137

Device Name: SIDEKICK® Circular Fixator System: Struts and Hinges

Indications For Use:

The SIDEKICK® Circular Fixator System: Struts and Hinges and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction or bony or soft tissue defonnities, and correction of segmental or nonsegmental bony or soft tissue defects. The SIDEKICK® Circular Fixator System: Struts and Hinges is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100137